Changes
to the
National Immunisation Programme

Dr Brenda Corcoran
National Immunisation Office
Objectives

• To describe the new primary childhood immunisation (PCI) schedule

• To discuss the role out of the new changes and information materials available

• To discuss issues relating to the HPV vaccination programme
The New PCI Schedule

All babies born on or after 1\textsuperscript{st} October 2016 will be offered the new PCI schedule
New schedule to start on 1\textsuperscript{st} December 2016 (at 2 months of age)
## The New PCI Schedule

<table>
<thead>
<tr>
<th>Change</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition of meningococcal B (MenB) vaccine</td>
<td>2, 4 and 12 months</td>
</tr>
<tr>
<td>Addition of rotavirus vaccine</td>
<td>2 and 4 months</td>
</tr>
<tr>
<td>Timing of MenC1</td>
<td>from 4 to 6 months</td>
</tr>
<tr>
<td>Timing of PCV3</td>
<td>from 12 to 13 months</td>
</tr>
<tr>
<td>Replacement of Hib and MenC with Hib/MenC (2</td>
<td>13 months</td>
</tr>
<tr>
<td>injections to 1 injection)</td>
<td></td>
</tr>
</tbody>
</table>
## The New PCI Schedule

<table>
<thead>
<tr>
<th>Age (months)</th>
<th>Current Schedule</th>
<th>Babies born on or after 1&lt;sup&gt;st&lt;/sup&gt; October 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine</td>
<td>Vaccine</td>
</tr>
<tr>
<td>2</td>
<td>6in1 + PCV</td>
<td>6in1 + PCV + MenB + Rotavirus</td>
</tr>
<tr>
<td></td>
<td>2 injects</td>
<td>3 + oral vaccine</td>
</tr>
<tr>
<td>4</td>
<td>6in1 + MenC</td>
<td>6in1 + MenB + Rotavirus</td>
</tr>
<tr>
<td></td>
<td>2 injects</td>
<td>2 + oral vaccine</td>
</tr>
<tr>
<td>6</td>
<td>6in1 + PCV</td>
<td>6in1 + PCV + MenC</td>
</tr>
<tr>
<td></td>
<td>2 injects</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>MMR + PCV</td>
<td>MMR + MenB</td>
</tr>
<tr>
<td></td>
<td>2 injects</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>MenC + Hib</td>
<td>Hib/MenC + PCV</td>
</tr>
<tr>
<td></td>
<td>2 injects</td>
<td>2</td>
</tr>
</tbody>
</table>
The New PCI Schedule

From 1st October 2016 until at least November 2017

2 schedules in place
– the old (current) schedule
– the new schedule
Meningococcal B (MenB) disease

- Caused by *Neisseria meningitidis*.
- Most common and serious clinical presentations
  - meningitis and septicaemia
- An important clinical and public health problem
  - rare but serious
  - disease onset is sudden and often dramatic
- A significant case fatality rate ~10%
- 1 in 10 survivors have long term complications including
  - brain damage, deafness, epilepsy, limb/digit loss, cognitive deficit
Meningococcal B (MenB) disease

- Most common in infancy and early childhood (0-4 years)
- A second smaller peak of incidence in adolescents and young adults
- Ireland has one of the highest notification rates of invasive meningococcal disease (IMD) in Europe

Confirmed cases in the EU/EEA, 2008-2012

Source: HPSC
MenB Vaccine

• A recombinant multi-component vaccine – Bexsero (GSK)
• **NOT** a live vaccine
• Safe and effective
• ~88% strains covered
• Widely given across Europe
• Introduced into the UK immunisation schedule in 2015
• Schedule
  – 2 + 1 schedule (not 3 +1 as per SmPC)
MenB Vaccine
Contraindications/ Precautions

Contraindications
- Anaphylactic reaction to a previous dose of vaccine
- Anaphylactic reaction to any constituent of vaccine including kanamycin and latex

Precautions
- Acute severe febrile illness
  - defer until well
- Known coagulation defects
  - caution with administration and apply pressure to the vaccine site for 1-2 minutes after vaccination
MenB Vaccine
Side effects

Very Common (1 in 10)
- Fever (>38°C)
- Tenderness / pain at injection site
- Skin rash
- Irritability
- Vomiting / diarrhoea
- Unusual crying

Uncommon (1 in 100 to 1 in 1000)
- High fever (>40°C)
- Seizures (including febrile seizures)
- Eczema

Rare (1 in 1,000 to 1 in 10,000)
- Urticaria
- Kawasaki’s disease
MenB Vaccine
Paracetamol

- Fever with MenB vaccine is a common side effect
- NIAC recommends **all babies** are given 3 doses of paracetamol at the 2 and 4 month MenB vaccines

<table>
<thead>
<tr>
<th>Liquid Infant Paracetamol (120mgs/5ml)</th>
<th>2 months</th>
<th>4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose 1</td>
<td>2.5 mls</td>
<td>At the time of injection</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td></td>
</tr>
<tr>
<td>Dose 2</td>
<td>2.5 mls</td>
<td>4-6 hours after dose 1</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td></td>
</tr>
<tr>
<td>Dose 3</td>
<td>2.5 mls</td>
<td>4-6 hours after dose 2</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td></td>
</tr>
</tbody>
</table>
MenB Vaccine
Paracetamol

- Will reduce the fever by ~ 50%
- If fever persists a further dose of paracetamol may be given i.e. 4 doses in 24 hours after vaccination
- If baby unwell or fever persists – parents should seek medical advice

Paracetamol (NOT Ibuprofen)
- Previously not recommended routinely
- Recent studies show NO evidence of a decrease in the immune response when paracetamol is given with the MenB vaccine and other PCI vaccines
- Recommendation supersedes PIL
- No increase in parental attendance if informed beforehand

- Not routinely given at the 12 month MenB vaccination (risk of fever is less)
Rotavirus Disease

- Very common viral infection causing diarrhoea and vomiting
- ~ 2,400 cases notified in Ireland each year
- Most in under 1 year age group

Age specific incidence rate per 100,000 population of notified rotavirus cases

Source: HPSC
Rotavirus Disease

- Estimated that all children infected with rotavirus by age 5
- Spreads very easily through hand to mouth contact and aerosol
- Symptoms
  - ~3-8 days
  - severe diarrhoea, stomach cramps, vomiting, dehydration, a low-grade fever
- Most babies and children recover at home
- Every year
  - ~ 920 children aged 0-4 require hospital treatment
  - Average length of stay 5 days
Rotavirus Vaccine

- Live attenuated ORAL vaccine
- Widely used routinely in Europe, UK, Australia and US
- Can be given with all other PCI vaccines
- Very effective (82-94%) in preventing rotavirus disease in young babies
- Reduces hospital admissions by ~ 70%
- Good safety profile and well tolerated in most babies
Rotavirus Vaccine

- Schedule
  - 2 doses at 2 and 4 months
- Give before injected vaccines

Instructions for administration of the vaccine:

1. Remove the protective tip cap from the oral applicator.
2. This vaccine is for oral administration only. The child should be seated in a reclining position. Administer orally (i.e. into the child’s mouth, towards the inner cheek) the entire content of the oral applicator.
Rotavirus Vaccine
Contraindications/ Precautions

Contraindications
• Confirmed anaphylactic reaction to a previous dose of rotavirus vaccines or its constituents
• Severe Combined Immunodeficiency Disorder (SCID)
• Previous history of intussusception
• Malformation of the gastrointestinal tract (?lead to intussusception)
• Hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption

Precautions (defer until well)
• an acute febrile illness
• an acute vomiting or diarrhoea illness
Severe Combined Immunodeficiency Disorder (SCID)

- Rare inherited condition => highly susceptible to infections
- More common in babies in some Traveller families (predominantly but not exclusively from the South East)
- About 1 case every year
- If diagnosed at or shortly after birth can be successfully treated with a bone marrow transplant (in the UK)

Need to ask parents
- Are there any diseases in the baby’s family that affect the immune system?
- Did anyone in either family need a bone marrow transplant as a baby?

If Yes => FBC required
Rotavirus Vaccine
Intussusception

- Very rare (approx 1 in 50,000 vaccinated babies)
- Intestinal prolapse leading to obstruction
- Most common in those aged 5months – 1 year
- ~1 in 1000 babies will get this condition naturally

- Symptoms
  - severe abdominal pain
  - worsens with time, ‘draw’ legs up
  - may get blood in stools, vomiting

- Needs urgent hospital treatment
Rotavirus Vaccine Schedule

Two doses at 2 and 4 months of age
• Best protection if given on time
• Increased risk of intussusception with increased age
  – **No** doses after 8 months and 0 days
  – Minimum interval between dose 1 and 2 is 1 month
  – Latest time to start dose 1 is 7 months
Order and site of vaccines

• Give MenB first in LEFT leg
• Give 6 in 1 followed by PCV in RIGHT leg

• To monitor any local adverse reactions
• To give most painful last (PCV)
Hib/MenC vaccine

• Menitorix (GSK)

• Used in UK PCI schedule

• Single prefilled syringe and vial

• Requires reconstitution
Information materials

- Information materials for parents
  - Updated
    - maternity leaflet
    - ‘Your child’s immunisation - A guide for parents’
    - Magnet
    - Immunisation passport
  - New tear pad at 6 weeks
  - Updated
    - tear pad with after vaccine care
    - information on website
Information materials

• Train the trainers day 18th May, Dublin
• Local roll out of training programme
• Information materials for health care professionals
  – Frequently Asked Questions document
  – Wheel for rotavirus vaccine doses and ages
  – Posters - new schedule, rotavirus schedule and paracetamol dosage
  – Updated
    • Guidelines for Vaccinations in General Practice
    • Immunisation Guidelines for Ireland (NIAC)
    • Updated information on website
HPV vaccine uptake
2010/2011 - 2016/2017

5000 more girls not vaccinated in 2015/16

<table>
<thead>
<tr>
<th>Year</th>
<th>Uptake</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010/11</td>
<td>81.9</td>
</tr>
<tr>
<td>2011/12</td>
<td>85.5</td>
</tr>
<tr>
<td>2012/13</td>
<td>84.2</td>
</tr>
<tr>
<td>2013/14</td>
<td>84.9</td>
</tr>
<tr>
<td>2014/15</td>
<td>86.9</td>
</tr>
<tr>
<td>2015/16</td>
<td>70.0</td>
</tr>
<tr>
<td>2016/17</td>
<td>50.0</td>
</tr>
</tbody>
</table>
ARE HPV VACCINES SAFE?
Reactions and Effects of Gardasil Resulting in Extreme Trauma

REGRET
Support Group

REGRET - Public Service Message from REGRET
HPV vaccination - Do you know the full facts? [11/08/2015]
HPV vaccination for 12 year old girl - Make us an offer...
Regret is an organisation of parents, just like you, who trusted what were were told.

REGRET GoFundMe campaign
[28/05/2016] REGRET GoFundMe campaign begins to help Irish families trying to cope with post-HPV vaccine illness. Tel: +353804582901 for info.

REGRET and the Aftermath of the HPV Vaccin...
THE MEANING OF REGRET
Cervical Cancer Vaccine - Is it safe? (Irish TV3 Documentary)

Four Irish families tell their stories about what getting the HPV Vaccine Gardasil has meant for them. TV3 documentary aired on 14/12/2013.
Concerns

- Vaccine safety
- Vaccine safety
- Vaccine safety
- Vaccine causes serious side effects
- Lack of information
- Consent process too rushed
- Distrust in HSE – link to Pharma
- Anti-establishment agenda
Vaccine uptake rate at 24 months 1999-2016

Target 95%

- 16 years
- Measles outbreaks
- Death and disability

Source: HPSC
HPV Vaccine Facts

Cervical Cancer in Ireland
• 6,500 women need hospital treatment pre-cancerous lesions
• > 280 (many young) women need treatment for invasive cancer
• 90 women die

Gardasil HPV vaccine prevents cancer developing
August 29th 2016 in Australia
• Professor Ian Frazer stated that after ten years of Gardasil HPV vaccine use “the number of new cases of cervical cancer in women has halved”

Best way to prevent cervical cancer = HPV vaccination + cervical screening
  ▶ Vaccine prevents precancerous growths and cancer
  ▶ Screening detects pre cancer or cancer of the cervix
HPV Vaccine Facts

Gardasil HPV vaccine is a safe vaccine with NO known long term side effects

• The safety profile studied for >13 years in >1 million people during clinical trials and since the vaccine was licensed in 2006.


• Since the programme started in 2010 to 30 September 2016 HPRA has received 1072 suspected adverse reactions/events
  • most of these reports are expected side effects
  • 14 - chronic fatigue syndrome
  • 10 - post viral fatigue
  • 3 - an auto immune condition
    Much less than expected
Chronic fatigue syndrome (CFS)

- known for over 200 years
- is 3-4 times more common in females and younger adolescents
- 10,000 cases in Ireland
- estimated prevalence rate in Ireland 0.2-0.4%
- 220,000 girls vaccinated (660,000 doses)
  => at least 440-880 cases expected

Reported numbers much lower than expected
Gardasil side effects

**Side effects seen after use**

- Scientific evidence of causation
- pain, redness or swelling in the arm
- headache
- nausea
- a mild fever
- itchy rash/ hives
- fainting
- serious allergic reactions very rare

**Side effects reported during general use**

- No scientific evidence of causation

---

**4. Possible side effects**

Like all vaccines and medicines, Gardasil can cause side effects, although not everyone gets them.

The following side effects can be seen after the use of Gardasil:

- Pain, redness or swelling in the arm
- Headache
- Nausea
- A mild fever
- Itchy rash/ hives
- Fainting
- Serious allergic reactions very rare

As with other vaccines, side effects that have been reported during general use include:
- Swollen glands (neck, armpit, or groin)
- Muscle weakness
- Abnormal sensations, tingling in the arms, legs, and upper body, or confusion (Gardasil-5 Syndrome)
- Acute disseminated encephalomyelitis
- Dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection at the injection site.

---

www.hpv.ie
CDC has carefully studied the risks of HPV vaccination. HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Potential Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancer Prevention</strong></td>
<td><strong>Chance of fainting</strong></td>
</tr>
<tr>
<td>Cervical, vaginal, and vulvar cancer in women</td>
<td></td>
</tr>
<tr>
<td>Anal cancer in men and women</td>
<td>Pain, redness, or swelling in the arm where the shot was given</td>
</tr>
<tr>
<td>Likely penile cancer in men</td>
<td></td>
</tr>
<tr>
<td>Likely oropharyngeal cancer in women and men</td>
<td></td>
</tr>
</tbody>
</table>

Actions

Plan
NIO
Irish Cancer Society
HSE Communications
NCSS

Information
School
Pharmacists
Social Workers
Nurses
GP
Parents
Politicians

Meetings
Public
WHO
Marie Keating Foundation
National Parents Council
Dept. of Education

Social
Video
National
Local
Media
HPV vaccine information

HPV Vaccines and Cervical Cancer

Website accredited by World Health Organization

HPV Vaccine Key Facts

HPV vaccine information

HPV Vaccine Facts

Human Papilloma Virus (HPV) Vaccine Information

www.immunisation.ie
www.hpv.ie
versus
Key points

• New PCI schedule for babies born on or after October 1st 2016

• 3 doses of infant paracetamol at and after 2 and 4 month Men B vaccines to reduce fever

• No dose of rotavirus after 8 months

• Concerted actions needed to overcome HPV vaccine safety concerns and prevent cervical cancer